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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,616	12/01/2000	Arlindo L. Castelhana	1919/60390-G/IPW/GJG/CMR	5191

7590

08/11/2003

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EXAMINER

MCINTOSH III, TRAVISS C

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 08/11/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

# **Office Action Summary**

Application N .

09/728,616

Applicant(s)

CASTELHANO ET AL.

Examiner

Traviss C McIntosh

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## **Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## **Status**

- 1) ☒ Responsive to communication(s) filed on 24 April 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

- 4) ☒ Claim(s) 76-110 and 114-133 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 76-98, 100-110 and 114-133 is/are rejected.
- 7) ☒ Claim(s) 99 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## **Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## **Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## **Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9 & 13.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

***Detailed Action***

***Election/Restrictions***

Applicant's election with traverse of Group I in Paper No. 13 is acknowledged. Applicant's arguments drawn to the restriction set forth have been fully considered and have been found persuasive. The compound, method of making and method of using will be examined in the instant case, 09/728,616. An action on the merits of claims 76-110 and 114-133 is contained herein below.

***Information Disclosure Statement***

Acknowledgement is made of the receipt of the IDS filed August 6, 2002 and April 24, 2003, however, the examiner has noted that the IDS filed February 15, 2002 and First supplemental IDS filed March 22, 2002 are not included in the file and the examiner has not been able to locate these. The examiner requests applicants resubmit the two IDS' again, with all non-patent literature for the examiner to consider and sign off on. The examiner can obtain all the patent documents.

***Claim Objections***

Claims 105 and 125-127 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 105 is a product by process claim drawn to: "the prodrug of claim 103 wherein said prodrug is metabolized *in vivo* by esterase

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catalyzed hydrolysis”. Where a product is metabolized, or by what is metabolized, is of no patentable import to the product as claimed. The product is treated on the merits of the product, not on processes associated with it. Claim 125 is drawn to “the composition of claim 124 wherein said therapeutically effective amount is effective to treat a respiratory disorder or a gastrointestinal disorder”. Claims 126 and 127 further limit the gastrointestinal disorders or respiratory disorders. Products are treated on the merits of the products, not on what the products are effective against. *In re Thorpe*, 227 USPQ 964, 966 (Fed Cir 1965).

Claims 77-99 are objected to because of the following informalities: none of the claims end in a period. Appropriate correction is required.

Applicant is advised that should claim 124 be found allowable, claim 132 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 124 is drawn to a composition comprising the compound of claim 76 or 99 and a carrier. Claim 132 is a packaged composition comprising the compound of claim 76 or 99 and a container and directions. The limitations of the composition being in a container and including instructions are of no patentable import to the composition as claimed.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 76-98 and 100-133 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 76 is indefinite wherein the claim reads, “wherein R<sub>5</sub> and R<sub>6</sub> are independently H, substituted or unsubstituted alkyl, or aryl”. It is unclear if applicants intend the group to be: H; substituted or unsubstituted alkyl; or aryl; or if applicants intend the group to be: H; substituted or unsubstituted alkyl; or substituted or unsubstituted aryl. Clarity is respectfully requested.

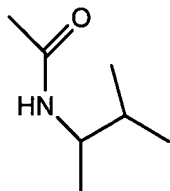
Claim 76 includes the limitation of “**substituted**...alkyl”. In the absence of the identity of moieties which are intended to be substituted, thus modifying an art recognized chemical compound of the alkyl moiety, described structurally or by chemical name, the identity of “substituted” would be difficult to ascertain. In the absence of said moieties, the claims containing the term “substituted” are not described sufficiently to distinctly point out that which applicant intends as their invention.

Claim 110 is indefinite wherein the claim reads, “...in a cell that is subject to **abnormal** stimulation of the A3 adenosine receptor...” It is unclear as to what is intended by “abnormal stimulation”. There is nothing set forth which defines normal, and there is no limit or degree of variance from the “normal” population which applicants set forth as that which defines what is considered the “abnormal” population.

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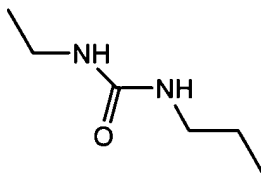
Claim 124 comprises the term “effective amount” and is indefinite as the claim fails to state the function which is rendered effective. See *In re Frederiksen*, 102 USPQ 35 (CCPA 1954).

Claim 77 is drawn to a 7-deazapurine compound which has the functional group:



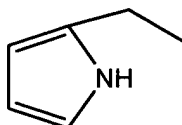
attached to the N-6 group of the 7-deazapurine, which lacks antecedent basis. This group is seen to be N-(1-ethyl-2-methyl-propyl)-acetamide, which is not a member of the Markush group of claim 76.

Claim 80 is drawn to a 7-deazapurine compound which has the functional group:



attached to the N-6 group of the 7-deazapurine, which lacks antecedent basis. This group is seen to be a 1-ethyl-3-propyl urea group, which is not a member of the Markush group of claim 76.

Claim 91 is drawn to a 7-deazapurine compound which has the functional group:



attached to the N-6 group of the 7-deazapurine, which lacks antecedent basis. This group is seen to be a 2-ethyl pyrrole group, which is not a member of the Markush group of claim 76.

Claims 91-98 are all drawn to specific compounds and all ultimately depend from claim 76. Claim 76 defines R<sub>5</sub> and R<sub>6</sub> as: H, substituted or unsubstituted alkyl, or aryl. While the term “substituted” is held indefinite as set forth supra, because it is unclear as to what groups are being substituted, claims 91-98 lack antecedent basis because the groups associated with R<sub>5</sub> and R<sub>6</sub> are not substituted or unsubstituted alkyl or aryl groups. The standard representation for substituted is something which replaces a hydrogen atom on the alkyl or aryl group, not a compound which links alkyl or aryl groups as O does in claims 91 and 94-98, and not as N-hetero rings or with N-linking groups as in claims 92 and 93.

Claim 133 is indefinite wherein applicants define the method as “treating the product of b) under suitable conditions to provide c)...” The method claims should be drafted to describe in definite terms what is intended in the process, not what the reaction with unknown agents is to accomplish. The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. Defining the method as “reacting a and b to get c, then changing c to d, and finally d to e”, does not define the method in a way to inform the public of the boundaries which are sought protection against.

All claims which depend from an indefinite claim are also indefinite. *Ex parte Cordova, 10 U.S.P.Q. 2d 1949, 1952 (P.T.O. Bd. App. 1989).*

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

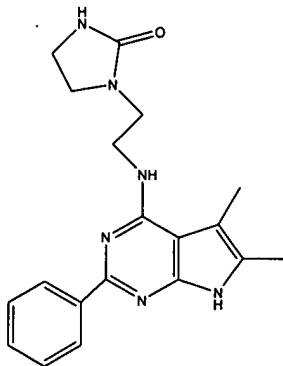
Claim 76 is rejected under 35 U.S.C. 102(a) as being anticipated by Campbell et al.

(“Selective A<sub>1</sub>-Adenosine Receptor Antagonists Identified Using Yeast *Saccharomyces cerevisiae* Functional Assays”, Bioorganic & Medicinal Chemistry Letters, vol. 9, no. 16, 8.16.1999, pp. 2413-18).

Claim 76 is drawn to a compound represented by the structure I below, when R<sub>5</sub> and R<sub>6</sub> are methyl, and R<sub>1</sub> is 2-imidazolidinone ethyl, the structure II is formed:



Campbell et al. disclose a compound 4i on page 2414, bottom table, and page 2415, product 4 of scheme 1 which is represented by the structure:



which is identical to the compound as represented by formula II above.



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The compound of Campbell et al. is seen to clearly anticipate the compound of claim 76.

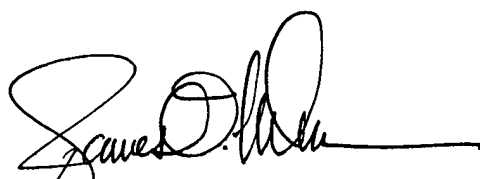
***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss McIntosh whose telephone number is 703-308-9479. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Traviss C. McIntosh  
August 8, 2003

  
James O. Wilson  
Supervisory Patent Examiner  
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